

Drug Review Decisions

September 18, 2003 Meeting

This following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the September 18, 2003, meeting, and the final decisions made after review of the recommendations.

	Description of Recommendation	Final Decision by the Commissioner and the Secretary
#1	Review of Aloxi (palonosetron) <ol style="list-style-type: none"> 1. Palonosetron (Aloxi) is <u>Equivalent</u>. (The drug is therapeutically equivalent in both safety and efficacy to the other members of this drug class). 2. Place a quantity limit of 4 vials per month consistent with the restrictions on the other 5-HT₃ antagonists, with larger quantities requiring a prior authorization. 3. Any new 5-HT₃ antagonists (new chemical entity) will be subject to a quantity limit sufficient for therapy of 4 chemotherapy cycles at the usual dose until reviewed by the P&T Committee. 	Recommendations approved
#2	Review of Xolair (Omalizumab) <ol style="list-style-type: none"> 1. Omalizumab is a Novel agent. (The drug is therapeutically equivalent in both safety and efficacy as compared to other available products for the treatment of asthma, but represents a new therapeutic option, which expands the treatment modality). 2. Require PA for omalizumab with approval for patients who meet the following criteria, which defines the group of patients with moderate to severe asthma and risk factors for significant asthma exacerbation episodes: <ol style="list-style-type: none"> a. Age ≥ 12 years. b. Positive skin test to perennial aeroallergen. c. IgE baseline level ≥ 30 IU/ml. d. FEV1 < 80% on maximal drug therapy. e. Failure of 60 days of therapy of inhaled corticosteroid in combination with a second controller agent, or contraindication. f. Significant asthma exacerbation episodes as evidenced by at least one of the following: <ul style="list-style-type: none"> • Systemic corticosteroid treatment (oral or injection) in the past year for treatment of an asthma exacerbation. • Hospitalization in the past year related to asthma exacerbation. • Intubation in the past year related to asthma exacerbation. 	Recommendations approved
#3	Class review of Proton Pump Inhibitors <ol style="list-style-type: none"> 1. All of the proton pump inhibitors are <u>Equivalent</u>. 2. Adopt the most cost-effective PPI as the preferred PPI and require prior-authorization for all other PPI's. Based on current utilization patterns and the average wholesale price (AWP) of the available drugs in this class, the most cost effective PPI's is omeprazole magnesium (Prilosec OTC). 3. Place a PA requirement on any new PPI's (new chemical entity) until reviewed by the P&T Committee. 	Delay implementation; re-review when supplemental rebate information becomes available.

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	4. Grandfather patients currently on PPI therapy until expiration of their Prior Authorization.	
#4	Tablet Splitting The P&T Committee recommends a special meeting to be held in October 2003 on the issue of tablet splitting. The Committee requests the attendance of the Executive Director and Chairperson of the Kentucky Board of Pharmacy.	Recommendation approved.